IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
GREENVILLE DIVISION

LIRLENE GARDLEY-STARKS **PLAINTIFF**

v. **CIVIL ACTION NO.: 4:10-CV-099-SA-JMV**

PFIZER, INC., et al. **DEFENDANTS**

MEMORANDUM OPINION

In this diversity action, Plaintiff Lirlene Gardley-Starks asserts numerous causes of action under Mississippi law, arguing that her ingestion of the prescription drug metoclopramide caused her to develop a neurological disorder known as tardive dyskinesia. Before the Court is a Motion for Summary Judgment [81] filed by Defendant Schwarz Pharma, Inc., and a Motion for Partial Summary Judgment [83][1] filed by Defendants Pfizer, Inc., and Wyeth Inc. (collectively, the "Brand Defendants"). Also before the Court is a Joint Motion to Dismiss for Failure to State a Claim [111] filed by Defendants Actavis Elizabeth, LLC; McKesson Corporation; Northstar RX, LLC; and PLIVA, Inc. (collectively, the "Generic Defendants").

FACTS & PROCEDURAL HISTORY

Metoclopramide is a prescription drug approved by the FDA for short term treatment of gastroesophageal reflux disease and diabetic gastroparesis. The FDA approved metoclopramide in 1980 under the brand name Reglan. In 1985, generic drug manufacturers began producing

[1]Plaintiff asserts claims against Wyeth arising from her alleged use of metoclopramide manufactured by ESI Lederle Inc., a former division of American Home Products Corporation which was later acquired by Wyeth. Wyeth's motion relates only to "Plaintiff's claims asserted against Wyeth on the basis that it is somehow liable for harm allegedly caused by other manufacturers' generic metoclopramide" and does not extend to claims resulting from Plaintiff's alleged use of metoclopramide manufactured by ESI Lederle, Inc.

metoclopramide. Brand name Reglan was manufactured by Defendant Wyeth[2] from 1989 to 2001. Defendant Schwarz acquired the rights to Reglan in December 2001, and manufactured and distributed the drug until 2008. The Generic Defendants, beginning in the mid-1980s, manufactured, sold and distributed generic metoclopramide.

Long term use of metoclopramide can cause a serious and permanent neurological condition known as tardive dyskinesia. In 1985, the drug's label was modified to warn that "tardive dyskinesia . . . may develop in patients treated with metoclopramide," and the drug's package insert added that "[t]herapy longer than 12 weeks has not been evaluated and cannot be recommended." In 2003, another labeling change was approved regarding metoclopramide use in geriatric patients. In 2004, the label was again changed to add that "[t]herapy should not exceed 12 weeks in duration." In 2009, the FDA ordered a boxed warning on metoclopramide—its strongest—which states: "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible . . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." Plaintiff alleges that Defendant PLIVA, a generic manufacturer, never updated its product labeling to reflect the 2003 and 2004 changes.

Between 2002 and 2008, Plaintiff was prescribed metoclopramide to treat her acid reflux, ulcers, and heartburn. Plaintiff alleges that her prescribing doctor relied upon information published in the package inserts for the drug and/or information published in the Physicians' Desk Reference (PDR). Plaintiff alleges that as a result of her long-term use of metoclopramide, she developed tardive dyskinesia. Plaintiff commenced the instant suit on August 9, 2010.

On February 28, 2011, this Court held a case management conference and stayed the case

[2]Pfizer acquired Wyeth in 2009 and is sued in its capacity as Wyeth's parent corporation.

pending the United Supreme Court's decision in PLIVA, Inc. v. Mensing, — U.S. —, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011). Mensing was decided on June 23, 2011, and as will be discussed more fully below, held that respondents' state-law failure to warn claims against generic manufacturers were preempted by federal law. Id. at 2572-73, 180 L. Ed. 2d 580.

On August 3, 2011, the Court lifted the stay to allow limited discovery regarding the issue of product identification. That discovery revealed that Plaintiff ingested generic metoclopramide manufactured by ESI Lederle, Northstar, PLIVA, and Purepac; however, there is no evidence that Plaintiff ever ingested brand name Reglan.

Thereafter, Defendants filed dispositive motions. The Brand Defendants argued that they were entitled to summary judgment due to the fact that Plaintiff never ingested brand name Reglan. The Generic Defendants sought judgment on the pleadings, asserting that Plaintiffs claims were preempted in light of Mensing. In response, Plaintiff filed a motion for leave to file an amended complaint, which was granted. On April 12, 2012, Plaintiff filed her first amended complaint, alleging that:

> This case involves Defendants' failure to warn physicians that use of metoclopramide should not exceed 12 weeks in duration . . . their sale of a defective product, their breach of express and implied warranties, and their negligence in continuing to market and sell Reglan/metoclopramide without complying with federal and state laws designed to protect consumers and in spite of their knowledge that numerous physicians were engaging in dangerous prescribing practices likely to result in injury to those who consumed the drug.

Plaintiff asserts the following claims under Mississippi law: (1) negligence, (2) strict liability, (3) breach of warranties, (4) misrepresentation, fraud, and suppression of evidence, and (5) gross negligence.

DISCUSSION

I. Brand Defendants

The Brand Defendants argue that, because it is undisputed that the Plaintiff never ingested their product (brand name Reglan), they are entitled to summary judgment. The Court agrees.

A. Summary Judgment Standard

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). "An issue of material fact is genuine if a reasonable jury could return a verdict for the nonmovant." Agnew v. Wash. Mut. Fin. Group, LLC, 244 F. Supp. 2d 672, 675 (N.D. Miss. 2003) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)).

"A party asserting that a fact cannot be or is genuinely disputed must support the assertion by: (A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials; or (B) showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." FED. R. CIV. P. 56(c)(1). "Conclusional allegations and denials, speculation, improbable inferences, unsubstantiated assertions, and legalistic argumentation do not adequately substitute for specific facts showing a genuine issue for trial." Oliver v. Scott, 276 F.3d 736, 744 (5th Cir. 2002).

The Court is not to weigh the evidence or engage in credibility determinations. Anderson,

477 U.S. at 249, 106 S. Ct. 2505; Deville v. Marcantel, 567 F.3d 156, 164 (5th Cir. 2009). "[T]he court must view the facts in the light most favorable to the non-moving party and draw all reasonable inferences in its favor." Deville, 567 F.3d at 164.

B. Analysis

The Brand Defendants argue that no matter how Plaintiff labels her claims, they are ultimately products liability claims, and because it is undisputed that Plaintiff never ingested a Brand Defendant product, her claims fail as a matter of law. Plaintiff responds that it is immaterial whether Plaintiff actually ingested name brand Reglan. Instead, she contends that her injury is due to her physician's reliance on false and misleading information disseminated by the Brand Defendants. Plaintiff asserts that she may still pursue claims against the Brand Defendants sounding in common law negligence and misrepresentation.[3]

By federal law, the manufacturer of a generic version of a drug must use the same label as that approved for the brand name drug. See Mensing, 131 S. Ct. at 2574, 180 L. Ed. 2d 580. Plaintiff argues that, because the manufacturers of generic metoclopramide are required to use a warning label identical to that approved for brand name Reglan, and that physicians rely upon the Brand Defendants' label when prescribing metoclopramide, regardless of whether a prescription is ultimately filled with a generic product, the Brand Defendants owe a duty of care towards the consumers of generic formulations of metoclopramide. The Brand Defendants respond that all of

[3]Plaintiff's response in opposition fails to address her claims for strict liability and breach of warranty. Accordingly, the Court deems those claims to be abandoned against the Brand Defendants. See Sanders v. Sailormen, Inc., 2012 WL 663021, at *3 (S.D. Miss. Feb. 28, 2012) ("Failure to address a claim results in the abandonment thereof."). In any event, such claims would fail due to Plaintiff's lack of use of a Brand Defendant product. See Gorman-Rupp Co. v. Hall, 908 So. 2d 749, 757 (Miss. 2005); Moore ex rel. Moore v. Miss. Valley Gas Co., 863 So. 2d 43, 46 (Miss. 2003); Cauley v. Sabic Innovative Plastics, U.S., L.L.C., 2012 WL 192303 (S.D. Miss. Jan. 23, 2012); Albritton v. Coleman Co., 813 F. Supp. 450, 455 (S.D. Miss. 1992).

plaintiffs claims, however styled, must fail as it is undisputed that plaintiff never consumed brand name Reglan. Moreover, the Brand Defendants argue that no duty to warn the users of a competitor's product exists under Mississippi law.

The Mississippi Products Liability Act ("MPLA") provides in pertinent part, that:

> (a) The manufacturer or seller of the product shall not be liable if the claimant does not prove by the preponderance of the evidence that at the time the product left the control of the manufacturer or seller:
>
> (i) 1. The product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or
>
> 2. The product was defective because it failed to contain adequate warnings or instructions, or
>
> 3. The product was designed in a defective manner, or
>
> 4. The product breached an express warranty or failed to conform to express factual representations upon which the claimant justifiably relied in electing to use the product; and
>
> (ii) The defective condition rendered the product unreasonably dangerous to the user or consumer; and
>
> (iii) The defective and unreasonably dangerous condition of the product proximately caused the damages for which recovery is sought.

MISS. CODE ANN. § 11-1-63. "Numerous district courts have recognized that the MPLA subsumes common law negligence and misrepresentation claims based on a defective product." Lashley v. Pfizer, Inc, — F. Supp. 2d —, 2012 WL 2459148, *4 (S.D. Miss. June 27, 2012) (citing Murray v. Gen. Motors, LLC, 2011 WL 3684517, *3 (S.D. Miss. Aug. 22, 2011), *aff'd*, — F. App'x —, 2012 WL 2005018 (5th Cir. 2012); McSwain v. Sunrise Med., Inc., 689 F. Supp. 2d 835, 844–46 (S.D. Miss. 2010); Jowers v. BOC Group, Inc., 2009 WL 995613, at *3-4 (S.D. Miss. Apr. 14, 2009), *vacated in part on other grounds*, Jowers v. Lincoln Elec. Co., 617 F.3d 346 (5th Cir. 2010); Walker

v. George Koch Sons, Inc., 610 F. Supp. 2d 551, 562-63 (S.D. Miss. 2009)). Furthermore, in any products liability action, "it is incumbent upon the plaintiff . . . to show that the defendant's product was the cause of the plaintiff's injuries." Moore, 863 So. 2d at 46.

Plaintiff cites the case of Lawson v. Honeywell Int'l., Inc., 75 So. 3d 1024 (Miss. 2011), for the proposition that she may pursue her claims for negligence and misrepresentation against the Brand Defendants regardless of the fact that she did not use a product manufactured by a Brand Defendant. In Lawson, the plaintiff filed suit against Honeywell International, a company which allegedly designed a defective seat belt buckle and then sold the design to Chrysler. Id. at 1026. The Plaintiff asserted claims against Honeywell under the MPLA for negligent design, as well as a claim for common law negligent design. Id. at 1025-26. The trial court granted summary judgment as to all of the plaintiff's claims against Honeywell, holding that the MPLA was the exclusive remedy for products liability actions in Mississippi, and it did not allow design-defect claims against designers who neither manufacture nor sell the product. Id. at 1026.

On appeal, the Mississippi Supreme Court determined that the MPLA applied only to "manufacturers" and "sellers," and that an entity which merely designed a product was neither. Id. at 1029-30. Accordingly, the court held that the MPLA did not preclude a common law claim for negligent design against the non-manufacturing, non-selling designer of the seat-belt buckle. Id. 1030. However, as the Brand Defendants point out, they are manufacturers and sellers of metoclopramide, just not the particular metoclopramide that injured the plaintiff. The court in Lawson was careful to limit its holding to non-manufacturing, non-selling designers of a product, and the Plaintiff has presented no authority applying Lawson in such an expansive manner as she suggests. The Court finds that Lawson is inapplicable to the present case and provides no support

for a negligence or misrepresentation claim against a Brand Name manufacturer for an injury caused by the use of a competitors' generic product.

Although the Mississippi Supreme Court has not yet addressed this issue, two federal courts applying Mississippi law post-Lawson have dismissed similar claims brought against the manufacturers of brand name drugs by users of their generic equivalents. First, in In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., a consolidated multi-district litigation ("MDL") products liability action, thirty-five plaintiffs from numerous states, including Mississippi, brought claims related to their ingestion of the drug propoxyphene against Xanodyne Pharmaceuticals, Inc., the manufacturer of Darvocet (the name brand version of propoxyphene). 856 F. Supp. 2d 904, 906-09 (E.D. Ky. 2012). The plaintiffs asserted various claims against Xanodyne including strict liability, negligence, breach of warranty, fraudulent non-disclosure, negligent misrepresentation, and fraudulent misrepresentation. Id. at 907. Xanodyne sought the dismissal of all claims against it brought by plaintiffs who did not ingest Darvocet manufactured, sold or distributed by Xanodyne. Id. The court granted Xanodyne's motion, finding that "[i]n every state implicated by Xanodyne's motions [including Mississippi], it is well-settled law that a 'threshold requirement of any products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury . . . There is no theory of product liability under which a defendant can be held liable for an injury caused by a product that it did not sell, manufacture, or otherwise supply." Id. at 908. The court rejected the plaintiffs' argument that their claims for misrepresentation were separate and apart from their products liability or failure-to warn claims, and found that even if the plaintiffs could bring such claims, they would fail because the name brand manufacturer of a drug owes no duty of care to the consumers of generic equivalents manufactured by other companies. Id. at 910-12.

Second, in an almost identical action, the United States District Court for the Southern District of Mississippi granted a motion for summary judgment brought by the name brand manufacturers of Reglan. Lashley v. Pfizer, Inc., — F. Supp. 2d —, 2012 WL 2459148, at *1-8 (S.D. Miss. June 27, 2012). The court found that "[p]recedent directs this Court to consider together, in a single inquiry, the adequacy of the warnings provided by the [brand defendants] as to Plaintiff's failure to warn, strict liability, misrepresentation, and negligence claims." Id. at *4 (citing Swayze v. McNeil Lab., 807 F.2d 464 (5th Cir. 1987)). The court concluded that because the plaintiff never ingested brand-name Reglan, "the Court is of the view that Defendants are entitled to summary judgment on Plaintiffs' claims for failure to warn, negligence, strict liability, and misrepresentation." Id. at *4-5.

The Court finds the reasoning of these cases persuasive. Moreover, the holdings of these cases are in line with the overwhelming majority of courts to consider the issue. See, e.g., Smith v. Wyeth, Inc., 657 F.3d 420, 424 (6th Cir. 2011) ("As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company."); Mensing v. Wyeth, Inc., 588 F.3d 603, 612-14 (8th Cir. 2009), *rev'd on other grounds sub nom.*, PLIVA, Inc. v. Mensing, 131 S. Ct. 2567 (2011); Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994); Hogue v. Pfizer, Inc., — F. Supp. 2d —, 2012 WL 4466609 (S.D. Ohio 2012); Phelps v. Wyeth, Inc, 857 F. Supp. 2d 1114 (D. Or. 2012); Strayhorn v. Wyeth Pharmaceuticals, Inc., — F. Supp. 2d —, 2012 WL 3217672 (W.D. Tenn. 2012); Metz v. Wyeth, LLC, 830 F. Supp. 2d 1291,1293 (M.D. Fla. 2011) ("The vast majority of courts, in Florida and elsewhere . . . have consistently held that consumers may not bring claims for negligence, fraud, strict liability,

misrepresentation, or breach of warranty against a brand name pharmaceutical manufacturer when the consumers only ingested generic versions of the drug manufactured by third parties").[4]

The Court concludes that Mississippi law, consistent with the vast majority of courts to consider this issue, would not recognize a cause of action—however styled—against a brand manufacturer for injuries caused by use of its competitors' generic product. Accordingly, the Court GRANTS the Brand Defendants' respective Motions for Summary Judgment and Partial Summary Judgment.

II. Generic Defendants

The Generic Defendants have filed a Motion to Dismiss pursuant to Rule 12(b)(6), arguing that all of Plaintiff's claims are preempted in light Mensing or otherwise fail to state a claim. The Court agrees.

A. Motion to Dismiss Standard

Under Rule 12(b)(6), the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit, 369 F.3d 464, 467 (5th Cir. 2004) (quoting Jones v. Greninger, 188 F.3d 322, 324 (5th Cir. 1999)). To overcome a Rule 12(b)(6) motion, plaintiffs must plead "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows

[4]The Brand Defendants have cited sixty-six decisions applying the law of twenty-three different jurisdictions holding that brand name manufacturers of a drug may not be held liable under any theory for injuries caused by the use of a generic manufacturer's product. See Docket [82], [102], [116]. Only two decisions have adopted the Plaintiff's theory of liability: the California intermediate Court of Appeals in Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2009) and the United States District Court for the District of Vermont in Kellogg v. Wyeth, 762 F. Supp. 2d 694 (D. Vt. 2010). However, these cases represent a distinct minority position.

the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009). This standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Id. It follows that "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" Id. at 679, 129 S. Ct. 1937 (quoting FED. R. CIV. P. 8(a)(2)).

The Supreme Court's decision in Iqbal provides a framework for examining the sufficiency of a complaint. First, the district court may "begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." Id. Second, "[w]hen there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." Id.

B. Discussion

Under federal law, generic and brand-name manufacturers of drugs have different drug labeling duties. Mensing, 131 S. Ct. at 2574, 180 L. Ed. 2d 580. All forms of labeling issued by generic drug manufactures are subject to a "duty of sameness" with respect to the labeling approved for the brand name version of the drug. Id. at 2574-75, 180 L. Ed. 2d 580. Federal law broadly defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). FDA regulations further define the term "label" to include:

> Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the "Physicians Desk Reference") for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer,

> packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor.

21 C.F.R. § 202.1(I)(2) (2012).

In Mensing, several plaintiffs asserted state tort claims against drug manufacturers for their alleged failure to provide adequate warning labels for generic metoclopramide. 131 S. Ct. at 2573–74, 180 L. Ed. 2d 580. The plaintiffs plead fourteen different counts, including failure to warn, fraud/misrepresentation, failure to monitor/test, violation of a state consumer protection statute, strict products liability, and breach of implied warranties. See Compl., Mensing v. Wyeth, Inc., 562 F. Supp. 2d 1056 (D. Minn. 2008) (No. 07–3919), at 27–49. The Court held that "federal drug regulations applicable to generic drug manufacturers directly conflict with, and thus preempt, these state-law claims," which were all predicated on a failure to warn theory. Mensing, 131 S. Ct. at 2572, 180 L. Ed. 2d 580. The Court reasoned that because federal law requires generic drug manufacturers to use drug warning labels identical to those used for the brand-name drugs, and because such warnings could not be changed without FDA approval, state tort claims against the generic manufacturers for failure to provide an adequate warning label are preempted by federal law. Id. at 2574, 180 L. Ed. 2d 580. The Court stated:

> If the [m]anufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking [the plaintiffs'] allegations as true, state law imposed on the [m]anufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. . . . Thus, it was impossible for the [m]anufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.

Id. at 2578, 180 L. Ed. 2d 580.

The Generic Defendants seek dismissal on the grounds that Mensing held that claims such

as those pursued by the Plaintiff are now preempted by federal law. Indeed, the majority of courts have continued to hold that state law tort claims asserted against generic drug manufacturers, no matter how styled, are ultimately based on a failure-to-warn and therefore preempted under Mensing. See e.g. Strayhorn v. Wyeth Pharm. Inc., — F. Supp. 2d —, 2012 WL 3261377 (W.D. Tenn. 2012); Lashley, 2012 WL 2459148 at *9-11; Moretti v. PLIVA, Inc., 2012 WL 628502 (D. Nev. Feb. 27, 2012); Morris v. Wyeth, Inc., 2012 WL 601455 (W.D. La. 2012); Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 658 (D. Md. 2012).

Nonetheless, the Plaintiff responds that the Mensing should be interpreted narrowly, and argues that "[w]hat was not considered in Mensing was the extent to which a generic manufacturer could be held liable for *selling* an unreasonably dangerous product, for accompanying its product with *false information* about potential risks associated with metoclopramide, and for *concealing* important safety information from the FDA, consumers, and the medical community."[5]

Unfortunately for the Plaintiffs, the Fifth Circuit recently left no doubt regarding the broad reach of Mensing in the recent opinion of Demahy v. Schwarz Pharma, Inc., — F.3d —, 2012 WL 6698692 (5th Cir. Oct. 25, 2012) (Demahy II). By way of background, in Demahy v. Actavis, Inc., 593 F.3d 428 (5th Cir. 2010) (Demahy I), the Fifth Circuit found that the plaintiff's failure-to-warn claims against a generic metoclopramide manufacturer (Actavis) were not preempted. Demahy I was consolidated with Mensing, and the Fifth Circuit's opinion was subsequently vacated by the

[5]As stated above, Mensing dealt with conflict or impossibility preemption. Plaintiff's argument that the preemption analysis in this case is or should be governed by various decisions of the United States Supreme Court and the Fifth Circuit Court of Appeals involving express preemption such as Cipollone v. Liggett Group, Inc., 505 U.S. 504, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992), Altria Group, Inc., Inc v. Good, 555 U.S. 70, 129 S. Ct. 538, 172 L. Ed. 2d 398 (2008), Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005), and Hughes v. Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011), is misplaced and unavailing.

Court. Mensing, 131 S. Ct. at 2572-73, 2582, 180 L. Ed. 2d 580. The case was remanded to the Fifth Circuit, which in turn remanded the case to the district court with instructions to enter judgment in favor of Actavis, and district court did so. Demahy II, 2012 WL 6698692, at *1-2. After the district court denied Demahy's motion to reconsider dismissal of all of her claims, Demahy appealed, arguing that the mandate from the Fifth Circuit encompassed "only . . . failure to warn claims that required a manufacturer to provide a warning that was different or in addition to the warnings appearing in the label for the brand-name version of the drug." Id. at *5. Demahy asserted that she had alleged "other claims" which were not preempted by the Mensing decision and therefore not encompassed by the Fifth Circuit's mandate following the same. Demahy's "other" claims, which are in many respects identical to the claims asserted in this case, included "(1) failure to warn claims that did not require the manufacturer to add to or differ its warnings from those appearing in the label of its brand-name counterpart; (2) claims arising under the [Louisiana Products Liability Act] for manufacturing defect, design defect, and breach of express warranties; (3) claims under the [Louisiana Unfair Trade Practices Act]; and (4) other claims arising from traditional tort concepts." Id. at *5 n.5.

In her brief, Demahy also, like the Plaintiff here, asserted that Mensing did not apply to claims that a "manufacturer distributed a misbranded drug with a label containing false information, that Actavis had failed to communicate the warnings appearing in the label for the brand-name drug, and that it had failed to use reasonable care in providing its warnings," as well claims for "the introduction into interstate commerce of a misbranded drug" and the failure of Actavis to "communicate information that was 'consistent with and not contrary to' the information appearing in the approved labeling for the drug through numerous available means." Brief of Plaintiff-

Appellant Julie Demahy at 26-27, Id., (No. 11-31073).

The Fifth Circuit affirmed the district court, finding that "it is true that the mandate addressed only her failure to warn claims . . . because Demahy's only remaining claims had been characterized by the district court, this Court, and Supreme Court as failure-to-warn claims." Id. The Fifth Circuit went on to state that "even if we were to find that these claims survived the mandate, or if we were to accept Demahy's assertion that the mandate was 'erroneous,' . . . we would still affirm the district court insofar the claims are, at base, failure-to-warn claims, which would be preempted in light of Mensing." Id. at *6.

Similarly, here, no matter how Plaintiff styles her theories of recovery, her claims ultimately relate to the Generic Defendants' alleged failure to warn about the side effect of metoclopramide. Therefore, all theories will be analyzed together under the umbrella of a failure to warn claim under Mississippi law. Swayze v. McNeil Labs., Inc., 807 F.2d 464, 467 (5th Cir. 1987). Under the MPLA, a manufacturer or seller is liable if "[t]he product was defective because it failed to contain adequate warnings or instructions." MISS. CODE ANN. § 11–1–63(a)(i)(2). The plaintiff must prove that, at the time the product left the control of the manufacturer or seller, "the manufacturer or seller knew or in light of reasonably available knowledge should have known about the danger that caused the damage for which recovery is sought and that the ordinary user or consumer would not realize its dangerous condition." § 11–1–63(c)(i). A warning is "adequate" if it:

> is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who

prescribes the drug, device or other product.

§ 11–1–63(c)(ii).

The Court finds that Plaintiff's claims against the Generic Manufacturers are subject to preemption or otherwise unavailing. None of Plaintiffs other theories discussed below persuade the court otherwise.

1. Failure-to-withdraw Theory

Plaintiff argues that Mensing did not address "the ability of a plaintiff to assert liability against a generic drug manufacturer for continuing to market and distribute its drug, despite the fact that it is misbranded." This theory was embraced by the Eighth Circuit in its original Mensing opinion which was later reversed by the Supreme Court. See Mensing v. Wyeth, Inc., 588 F.3d 603, 611 (8th Cir. 2009), *rev'd*, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could propose a label change, they could have simply stopped selling the product"). Although the Supreme Court did not specifically address this argument in its opinion, on remand, the Eighth Circuit vacated that portion of its opinion. See Mensing v. Wyeth, Inc., 658 F.3d 867, 867 (8th Cir. 2011). The "failure-to-withdraw" theory of liability has since been rejected by numerous other courts. See e.g. Jacobsen v. Wyeth, LLC, 2012 WL 3575293, at *9-11 (E.D. La. Aug. 20, 2012); Cooper v. Wyeth, 2012 WL 733846, at *6 (M.D. La. Mar. 6, 2012); In re Darvocet, Darvon and Propoxyphene Prod. Liability Litigation, 2012 WL 718618, at *3 (E.D. Ky. Mar. 5, 2012); Moretti v. Mutual Pharm. Co., 852 F. Supp. 2d 1114, 1118 (D. Minn. 2012); Gross v. Pfizer, Inc., 825 F. Supp. 2d 654, 658-59 (D. Md. 2011); but see Bartlett v. Mutual Pharm. Co., Inc., 678 F.3d 30, 37-38 (1st Cir. 2012) (design defect claim against generic drug manufacturer was

not preempted, despite duty of sameness regarding composition, because "it certainly can choose not to make the drug at all"), *cert granted*, — S. Ct. —, 2012 WL 3134353 (Nov. 30, 2012) . The Court finds, consistent with the great weight of authority, that any claims related to the Generic Defendants' failure to withdraw metoclopramide from the market are preempted.

2. Failure to Communicate to Warnings

Plaintiff next asserts that the Generic Defendants may held liable for failing to communicate the 2003 and 2004 labeling changes to Physicians and consumers through the use of "Dear Doctor" letters or by other methods. Plaintiffs argue that Mensing only held that generic manufacturers could not send "Dear Doctor" letter that contained new or additional warnings, and the Court did not consider whether a generic manufacturer could use such letters or other methods to apprise health care professionals of information appearing in approved labeling. However, the Mensing decision itself forecloses this argument:

> A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling. Moreover, if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly "misleading."... Accordingly, we conclude that federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters.

Mensing, 131 S. Ct. at 2576, 180 L. Ed. 2d 580. As stated by one district court, "labeling is so broadly defined that it encompasses nearly every form of communication with medical professionals . . . Simply put, the generic drug defendants are not allowed to alter the labeling adopted by the brand manufacturers in any way." Del Valle v. PLIVA, Inc., 2011 WL 7168620, at *6 (S.D. Tex. Dec. 21, 2011) (citing Mensing, 131 S. Ct. at 2576, 180 L. Ed. 2d 580; and 21 C.F.R. § 202.1(I)(2)).

The Court finds, consistent with the majority of other courts to consider this issue, that any

claims stemming from the generic defendants alleged failure to communicate additional warnings through some method other than their package inserts are preempted. Demahy II, 2012 WL 6698692, at *5-6 ("failure to warn claims that did not require the manufacturer to add to or differ its warnings from those appearing in the label of its brand-name counterpart" are still preempted); Strayhorn v. Wyeth Pharm., Inc., — F. Supp. 2d —, 2012 WL 3261377, at *15 (W.D. Tenn. 2012) (Plaintiffs' assertion that the Generic Defendants could have sent Dear Doctor letters or other communications to physicians or patients is also preempted"); Moore v. Mylan Inc., 840 F. Supp. 2d 1337, 1349 n.11 (N.D. Ga. 2012); Moretti, 2012 WL 628502, at *2-6; Guarino v. Wyeth LLC, 823 F. Supp. 2d 1289, 1292-93 (M.D. Fla. 2011).

3. Failure to Conduct post-marketing surveillance and reporting

Plaintiffs also allege that the Generic Defendants violated federal law by "fail[ing] to perform post-marketing surveillance for their drugs, to ensure the accuracy of statements appearing in their package insert, to review all adverse drug event information, and to report important information relating to the safety of their products." These types of claims have been repeatedly rejected as being preempted in light of Mensing. As recently explained by another court in this district:

> To the extent any investigation, testing, or marketing surveillance would have revealed the dangers of the drug, that knowledge would have been helpful only to the extent it was communicated through labeling—which would not have made any difference as long as the Generic Defendants were following the FDA's labeling regulations. The Generic Defendants could not have unilaterally improved the labeling of the drug any further even if they had wanted to. Thus, the Court holds that all of the Plaintiffs' claims against the Generic Defendants are preempted under federal law.

Truddle v. Wyeth LLC, 2012 WL 3338715, at *4 (N.D. Miss. Aug. 14, 2012); see also Moretti, 852

F. Supp. 2d at 1118 (finding such claims preempted as "virtually identical claims were asserted in the Mensing case"); Moretti v. PLIVA, 2012 WL 628502, at *6 (D. Nev. Feb. 27, 2012) (finding claims based on "failure to conduct post-marketing surveillance or report adverse events" to be preempted). The Court agrees with the reasoning of these cases and finds these claims to be preempted.

4. Failure to Update Label

Finally, Plaintiff alleges that PLIVA never updated its label to incorporate the 2003 and 2004 changes. The Generic Defendants respond that Plaintiff's claims regarding PLIVA's failure to implement the labeling changes represent impermissible attempts to enforce the FDA regulations. See 21 U.S.C. § 337(a); Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 349 n.4, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). However, to the extent Plaintiff asserts that PLIVA could have complied with a state law duty to warn by implementing the 2003 and 2004 label changes, such claims may arguably not be preempted by Mensing. As one district court recently stated, "reasonable arguments can be presented for and against the proposition that the claim is preempted." Fullington v. PLIVA, 2012 WL 1893749, at *6 (E.D. Ark. May 23, 2012) (ultimately declining to reach issue). On one hand, if PLIVA could satisfy its state law duty to warn by changing its product label to match that of brand name Reglan, then there would be no violation of the "duty of sameness," and impossibility preemption would not apply.

However, this issue was raised before the Supreme Court in Mensing, as well as the Eight Circuit following remand, but neither court carved out an exception for cases when the generic drug's label is not updated to match the brand label. Del Valle v. PLIVA, Inc., 2011 WL 7168620, at *8 (S.D. Tex. Dec. 21, 2011). This argument was also presented to the Sixth Circuit in Smith, yet

the Smith court found all of plaintiffs' claims preempted without specifically addressing this issue. See Gross, 825 F. Supp. 2d at 660 (noting that "[i]dentical arguments were made by the plaintiffs in supplemental briefings to the Sixth and Eighth Circuits, and both courts nevertheless dismissed the plaintiffs' claims based on preemption under Mensing").

In light of this lack of clear precedent, several district courts have allowed such claims to proceed. See e.g. Lyman v. Pfizer, Inc., 2012 WL 2970627 (D. Vt. July 20, 2012); Cooper, 2012 WL 733846, at *3-4; Fisher v. Pelstring, 817 F. Supp. 2d 791, 805 (D.S.C. 2011) ("The Court finds that this possible deviation in PLIVA's label for generic metoclopramide, which both parties indicate exists, is sufficient to conclude that plaintiffs' claims are not entirely preempted").

However, other courts have reached the opposite conclusion. See e.g. Strayhorn, 2012 WL 3261377, at *15-16 (finding that "all of Plaintiffs' claims based on the Generic Defendants' failure to conform their labels to those of the Brand Name Defendants are preempted or otherwise unavailing"); Bell v. Pliva, Inc., 845 F. Supp. 2d 967, 971 (E.D. Ark. 2012) (finding that because only the brand-name manufacturer can modify the information provided to physicians, "PLIVA's failure to update its consumer-level warnings does not vitiate its preemption defense"); Fulgenzi v. PLIVA, Inc., — F. Supp. 2d —, 2012 WL 1110009 (N.D. Ohio 2012) ("the requirement that the generic manufacturer's label match that of the namebrand flows from federal regulations . . . . There is no private cause of action for violations of FDA regulation"); Brinkley v. Pfizer, Inc., 2012 WL 1564945 (W.D. Mo. Apr. 12, 2012) (finding claims preempted).

The Court finds that, even if Plaintiff's claims related to PLIVA's failure to update its label are not preempted, Plaintiff nonetheless fails to state a claim upon which relief may be granted. Specifically, Plaintiff's First Amended Complaint fails to plausibly allege causation between

PLIVA's failure to update its label and Plaintiff's injuries. Mississippi adheres to the "learned intermediary" doctrine, which holds in part "'that where prescription drugs are concerned, a manufacturer's duty to warn only extends to physicians and not to laymen.'" Lashley, 2012 WL 2459148 at *6 (quoting Windham v. Wyeth Laboratories, Inc., 786 F. Supp. 607, 611 (S.D. Miss. 1992)).

Plaintiff fails to allege that her physician ever relied on PLIVA's labeling when prescribing metoclopramide. Instead, Plaintiff alleges that her physician relied on the package inserts for brand name Reglan and the PDR entry disseminated by the Brand Defendants. Moreover, Plaintiff asserts that "PLIVA never provided a copy of its label . . . to ANY physician" and "the only information [the Generic Defendants] provided about their products was contained in the package insert attached to the bulk containers of metoclopramide shipped to pharmacies . . . effectively ensur[ing] that no physician or consumer" would be provided with the warnings. Because Plaintiff has failed to plausibly allege that the failure of PLIVA to update its label to match that of the Brand Defendants was the proximate cause of Plaintiff's injuries, these claims are due to be dismissed. See Del Valle, 2011 WL 7168620, at *8 (dismissing claims against generic metoclopramide manufacturers where "[plaintiff] plead no facts to show that the purported failure of PLIVA and Teva to update the label . . . caused her injuries"); Windham, 786 F. Supp. at 613; see also Deese v. Immunex Corp., 2012 WL 463722, at *5 (S.D. Miss. Feb. 13, 2012) (dismissing failure-to-warn claim as inadequately pleaded where plaintiff "fell short of alleging that an adequate warning would have kept his physician from prescribing Enbrel"). And, as discussed above, to the extent Plaintiff alleges that a generic drug manufacturer should have issued warnings to physicians beyond its FDA approved labeling, such claims are preempted.

5. Defective Design

Finally, to the extent Plaintiff is pursuing a design defect against the Generic Defendants, the Court finds that such claims are also preempted. The "duty of sameness" requires a generic drug to be bioequivalent to its name-brand counterpart. Therefore, "a generic manufacturer cannot alter the design of a drug without violating federal law and this duty of sameness." Jacobsen, 2012 WL 3575293 at *10, n.143; see also Demahy II, 2012 WL 6698692, at *6 ("we are persuaded that Demahy's design defect claim would be preempted"); In re Accutane Products Liability, 2012 WL 3194952, at *2-3 (M.D. Fla. Aug. 7, 2012) (holding design defect claims against generic drug manufacturer preempted); Lashley, 2012 WL 2459148, at *10-11 (same).

CONCLUSION

For all of the reasons set forth above:

Defendant Schwarz Pharma Inc.'s Motion for Summary Judgment [81] is GRANTED;

Defendants Pfizer, Inc. and Wyeth, Inc.'s Motion for Partial Summary Judgment [83] is GRANTED; and

The Generic Defendants' Motion to Dismiss [111] is GRANTED. .

SO ORDERED on this, the 10th day of January, 2013.

/s/ Sharion Aycock
UNITED STATES DISTRICT JUDGE